



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

Prospective Grant of an Exclusive Patent License: Natural product based nanoparticles as dietary management and/or treatment of inflammatory related diseases.

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to MaDu, LLC located at 2025 Broadway, Suite 23E, New York, NY 10023.

**DATES:** Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE FIFTEEN (15) DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Michelle A. Favila, Ph.D., Technology Transfer Manager, National Institutes of Health, NCI Technology Transfer Center by email ([michelle.favila@nih.gov](mailto:michelle.favila@nih.gov)).

### SUPPLEMENTARY INFORMATION:

#### Intellectual Property

HHS Ref No. E-154-2018-0: Binary Lipid Bilayer-Containing Vesicles Comprising Embedded Cytotoxic Agents and Methods of Making and Using the Same :

1. United States Provisional Patent Application No. No. 62/697,287 filed July 12, 2018.  
[HHS Ref No. E-154-2018-0-US-01]
2. International Patent Application No. PCT/US2019/041464 filed July 11, 2019.

[HHS Ref. No. E-154-2018-0-PCT-02]

3. Canadian Patent Application No. 3106008 filed July 11, 2019. [HHS Ref No. E-154-2018-0-CA-03]
4. European Patent Application 19746275.7 filed July 11, 2019. [HHS Ref No. E-154-2018-0-EP-04]
5. Japanese Patent Application 2021-500734 filed July 11, 2019. [HHS Ref No. E-154-2018-0-JP-05] and
6. United States Patent Application 17/259,499 filed January 11, 2021 [HHS Ref No. E-154-2018-0-US-01]

The patent and patent application rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and will be less than the full patent term and the field of use may be limited to the following: Development and commercialization of the Binary Lipid Nanoparticle encapsulating known natural products curcumin, vitamin D, and/or L-serine that are Generally Recognized as Safe for use as medical foods, as defined by the FDA, or over-the-counter products for the management of pain and inflammatory-related diseases. The prospective licensee plans to develop Medical Foods, which is defined by the FDA as “food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”

This technology discloses formulation and methods of using novel stealth lipid nanoparticles that have a high stability and payload capacity. Combination of these nanoparticles with selected agents may have various medical applications for cancer and anti-inflammatory indications.

This notice is made in accordance with 35 U.S.C. § 209 and 37 C.F.R. § 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may

be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. § 209 and 37 C.F.R. § 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. § 552.

Dated: April 16, 2021.

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Richard U. Rodriguez,  
Associate Director,  
Technology Transfer Center,  
National Cancer Institute.

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